IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Patent Application of

KALLOO et al — Atty. Ref.: 2784-25

Serial No. 09/815,336 — TC/A.U.: 3739

Filed: March 23, 2001 — Examiner: Shay, David

For: METHODS AND DEVICES FOR DIAGNOSTIC AND THERAPEUTIC INTERVENTIONS IN THE PERITONEAL CAVITY

* *

April 10, 2008

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

Applicant submits herewith their Brief on Appeal pursuant to 37 CFR §41.37.

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(I) REAL PARTY IN INTEREST

The real party in interest is the assignee, JOHNS HOPKINS UNIVERSITY, organized and existing under the laws of the State of Maryland.

(II) RELATED APPEALS AND INTERFERENCES

On information and belief there are no other prior or pending appeals, interferences, or judicial proceedings (past or present), known to appellant, the appellant's legal representative, or assignee, which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

(III) STATUS OF CLAIMS

Claims 1-2, 4-19, 21-22 and 36 remain pending. Claims 1-2, 4-19, 21-22 and 36 have been rejected. The Examiner's April 16, 2007 rejection of claims 1-2, 4-19, 21-22 and 36 is being appealed. A current listing of the claims that are the subject of this Appeal is presented in the Claims Appendix of this Brief.

(IV) STATUS OF AMENDMENTS

A Request for Reconsideration was filed on November 26, 2007, after the Notice of Appeal was filed on October 12, 2007, in response to the Examiner's Official Action of April 16, 2007.

On December 27, 2007, the Examiner issued an Advisory Action advising that the Request for Reconsideration had been considered but did not place the Application in condition for allowance.

(V) SUMMARY OF CLAIMED SUBJECT MATTER

The present invention relates to a technique for accessing the peritoneal cavity via the wall of the digestive tract so that examination of and/or a surgical procedure in the peritoneal cavity can be conducted via the wall of the digestive tract with the use of a flexible endoscope.

Thus, and more specifically, as defined in independent claim 1, the sole independent claim that is the subject of this appeal, the invention provides a method for accessing an interior of a cavity of a mammal, said method comprising: positioning an elongated flexible conduit 10,12 to extend from an exterior of the mammal through a natural orifice into and along at least a portion of the digestive tract to a target wall segment in the digestive tract (page 5, lines 19-23; page 7, line 29 – page 8, line 4; Figure 6); forming an incision in said target wall segment (page 7, line 11; page 8, line 5 – page 9, line 6; page 12, lines 13-22); advancing a distal end of said flexible conduit so that the distal end of said conduit extends through said wall (page 7, lines 10-11; Figure 10); after forming said incision and advancing the distal end of said flexible conduit through said wall, anchoring 22,24 said distal end with respect to said wall (page 7, lines 12-18; page 13, line 21 – page 14, line 13; Figures 10-11); advancing an endoscope 40 through said conduit 10,12 so that a distal end of said endoscope is disposed adjacent or distal to said distal end of said conduit (page 7, lines 18-21; page 14, lines 14-16; Figures 11-12); viewing at least one of a tissue and an organ within said cavity (page 7, lines 20-21; page 14, lines 16-18); releasing said anchor 22,24 (page 7, line 22, page 15, lines 17-19); withdrawing said conduit 10,12 and said endoscope 40 through said wall (page 7, line 23, page 15, lines 20-22); and closing 68 said incision 66 (page 7, lines 24-25, page 15, line 23 – page 16, line 20; Figures 13-17), further comprising, after said forming an incision and before said advancing said conduit 12, dilating said incision (Figures 8-9) to facilitate passage of said conduit

therethrough, wherein said dilating comprises dilating with an inflatable balloon 54 (page 9, line 17 – page 10, lines 20; page 13, lines 4-19).

(VI) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 2, 4, 5, 7-13, 15-19, 21, 22 and 36 stand rejected under 35 U.S.C. 103(a) as being unpatentable under Wilk in combination with McNeely, et al.

Claims 6 and 14 stand rejected as unpatentable over Wilk in view of McNeely and further in view of Laufer.

(VII) ARGUMENT

A. Claims 1, 2, 4, 5, 7-13, 15-19, 21, 22 and 36 are patentable as not having been obvious under 35 USC 103(a) from Wilk in combination with McNeely et al.

Independent Claim 1, the sole independent claim pending in this Application, relates to a method including forming an incision in a target wall segment in the digestive tract and advancing a distal end of a flexible conduit so that the distal end of the conduit extends through said wall. Claim 1 also provides that after forming the incision and before advancing the conduit through it, the incision is dilated with an inflatable balloon to facilitate passage of the conduit therethrough. Further, Claim 1 provides that after the incision is formed and after the distal end of the flexible conduit is advanced through the wall, the distal end of the conduit is anchored with respect to the wall.

As will be understood from a close examination of Wilk, Wilk does not teach advancing the distal end of his flexible conduit through an incised target wall segment of the digestive tract and then anchoring the distal end with respect to the wall. Indeed, the flexible conduit Wilk teaches as advanced into the stomach is never advanced through the wall of the stomach. Rather, it is "anchored" to the wall by applying suction to hold the conduit against the wall. Wilk does not specifically disclose how a seal is maintained between the tubular member and the wall, although it is schematically illustrated in Figure 5A. Wilk does teach inserting a hollow needle through the tubular member and through the wall into the abdominal cavity, inserting an incising instrument, and moving the distal end of an endoscope through the perforation, but the tubular member itself is never passed through the incision. Rather, it is anchored against the inner wall surface.

Because Wilk does not teach advancing a distal end of a flexible conduit through an incision in the target wall segment and, after advancing the flexible conduit through

the wall, anchoring the distal end of the flexible conduit with respect to that wall, Wilk does not teach a method as claimed "except the specific mentioning of dilating the opening after it is made" as alleged by the Examiner.

The Examiner cites the secondary reference to McNeely as allegedly teaching a method of dilating a stomach wall. Actually, it is believed that McNeely has been mischaracterized in this regard. Indeed, McNeely relates to the insertion of a gastrostomy catheter through a passageway formed through both the abdominal and stomach walls of the patient. In McNeely, the abdominal wall is anchored at two points with respect to the stomach wall, and then a passage for the gastrostomy catheter is created, including using a dilation catheter assembly. Thus, McNeely does not simply teach a method of dilating the stomach wall, but relates to a procedure required for placement of a gastrostomy catheter through both the abdominal wall and the stomach wall.

As noted above, Wilk teaches passing various incising devices through a tubular member that is anchored by suction to the inner wall surface of the stomach. Wilk does not relate to the placement of a gastrostomy catheter and McNeely does not teach or in any way suggest that dilation of the incision(s) made in Wilk would be necessary or desirable. It is therefore respectfully submitted that, in the first instance, the Examiner has not established that the skilled artisan, in the absence of Applicant's disclosure, would have been taught by McNeely that dilation of the Wilk incision would have been necessary or desirable. In any event, even if an incision made by Wilk through the stomach wall is dilated with a dilation catheter in view of McNeely's teachings, the resulting combination of Wilk and McNeely does not teach or suggest the method specifically recited in Applicant's independent claim 1 because the combination of Wilk and McNeely does not teach passing the tubular member of Wilk through a dilated incision in the digestive tract wall, and then anchoring the tubular member with respect to the stomach wall. As noted above, Wilk teaches anchoring the tubular member to

the inner surface of the stomach wall before any incision is made, and never teaches passing the tubular member through the stomach wall.

In the Examiner's Advisory Action of December 27, 2007, the Examiner asserts that while Wilk does not pass the distal end of the flexible conduit through the stomach wall as part of the sealing process, this is taught by McNeely in Figure 1 thereof. In this regard, the Examiner apparently overlooks or ignores the fact that McNeely relates to placement of a gastrostomy catheter system where the gastric wall is anchored to the abdominal wall by a plurality of tethers or anchors 18 and a long term gastrostomy catheter is disposed between them. Thus, McNeely does not relate to a short term surgical procedure of the type taught by Wilks, much less a procedure where access is through the digestive tract via a tube abutted to the stomach wall, as taught by Wilk. As such, McNeely does not motivate the skilled artisan to modify Wilk in this regard.

The Examiner also asserts the passage of the flexible conduit does not appear to be critical to the invention, citing the paragraphs spanning pages 6 and 7. In this regard, the Examiner apparently overlooks the fact that the passage of the flexible conduit is a very specific limitation of applicant's independent claim 1 and, therefore, cannot be disregarded by the Examiner in evaluating the patentability of the claim.

Furthermore, the Examiner's assertion that one having ordinary skill in the art would obviously seal Wilk's perforation is not well taken. Wilk teaches sealing his tube with respect to the inner wall surface of the digestive tract and does not in any way teach or suggest a need for any further sealing. Wilk simply teaches sealing engagement on one side only of the wall of the digestive tract and passing instruments through the tube to the incision. Any characterization thereof as requiring further sealing is apparently motivated only by the Examiner's hindsight knowledge of applicant's disclosure.

For all these reasons, Claim 1 is not obvious from Wilk taken in combination with McNeely.

With respect to claims 13 and 15, Applicant respectfully traverses the Examiner's summary conclusion that it would have been obvious to situate the dilating balloon on a needle knife conduit. Firstly, neither Wilk nor McNeely teach or suggest an endoscopic knife device comprising a conduit within which a needle-knife is disposed. Moreover, neither of these documents in any way teach or suggest the unique combination of Claims 18 and 19, wherein the conduit of the needle-knife receives a guide wire and an inflatable balloon is provided on the conduit of the needle-knife device. Wilk refers only generally to a piercing needle at the distal end of the tubular instrument and endoscopic incising instruments, but nowhere describes a needle knife retractable through a needle knife conduit so as to be exchangeable with a guide wire and/or a dilatable balloon on the needle knife conduit. McNeely teaches an introducer needle for penetrating the abdomen and stomach and for placement of the guide wire, and then the introducer needle is removed and then a dilation catheter is separately placed over the guide wire. Thus, McNeely also fails to teach or suggest incorporating the dilatable balloon on the conduit through which the needle knife selectively extends.

In the Advisory Action, the Examiner acknowledges that neither Wilk nor McNeely provide the recited structure, but the Examiner summarily concludes that the combination does. Applicant respectfully disagrees. As noted above, the Examiner is proposing to combine two references relating to very different procedures. McNeely relates to the placement of a gastrostomy catheter where the incision site is visualized from the exterior of the abdomen. The incision is simply made by directly inserting a needle, not through any catheter much less a dilating catheter. Wilks on the other hand does not teach or suggest any need for dilation when penetrating the wall of the digestive tract, much less teach how this could be accomplished. Even if a needle is used to form the incision in Wilk, McNeely does not teach or suggest that the needle

should be inserted through a dilating catheter. Rather, McNeely teaches insertion of a needle, insertion of a guide wire through the needle, removal of the needle, and then feeding dilating catheters over the guidewire. At no point does McNeely teach or in any way suggest feeding a needle knife through a dilating conduit and, therefore, Wilks modified in view of McNeely would not provide such a procedural step either.

The Examiner says that applicant's assertions that the dilation balloon is not on the conduit of the needle knife is erroneous in view of the disclosure of McNeely at column 5, line 2 to column 6, line 52 and Figures 3-8 of McNeely. It is believed in this regard that it is the Examiner's interpretation of McNeely that is clearly erroneous. At column 5, line 65 – column 6, line 16, it is clearly explained that a small incision is made, then an introducer needle is advanced through the center of the incision, a guidewire is passed through the needle, the introducer needle is withdrawn and then the plurality of catheter type dilators are passed over the guidewire and then, ultimately, the dilation catheter 30 having a balloon is advanced and inflated to complete the dilation. It is abundantly clear from this passage of McNeely that there is no teaching or suggestion whatsoever of a needle knife inserted through a dilating catheter having a balloon.

Clearly, then, the specific instrument used in the method of the invention as set forth in Claims 13, 15, 17, 18 and 19, is nowhere taught or suggested by the combination of Wilk and McNeely, and the Examiner has failed to establish that a needle knife device as recited in the method of these dependent claims was known or would have been an obvious choice at the time of Applicant's invention.

For all the reasons advanced above, reconsideration and withdrawal of the rejection over Wilk and McNeely is solicited.

For all the reasons advanced above, it is respectfully submitted that the Examiner's rejection of applicant's claims based on Wilk and McNeely is without merit.

B. Claims 6 and 14 are patentable as not having been obvious under 35 USC 103(a) from Wilk in combination with McNeely and further in view of Laufer.

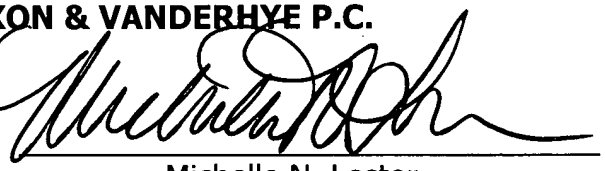
The Examiner asserts that in view of Laufer it would have been obvious to use a cauterizing incision device and/or balloon sealing means in the method of Wilk/McNeely. Applicant respectfully but strongly disagrees. As noted above, Wilk clearly teaches, and it is evidently central to Wilk's method, that his tubular member is sealed by suction to the inner wall of the patient's stomach. Wilk never teaches or suggests that the tubular member should be passed through the stomach wall. Quite the contrary, Wilk teaches only that instruments pass through the suction sealed tubular member to and through the stomach wall. Under these circumstances, it would not have been obvious to provide balloons on Wilk's tubular member or to anchor Wilk's tubular member using balloons. Wilk's simply relates to an entirely different attachment process, and, without the benefit of knowledge of Applicant's disclosure and claims, the skilled artisan would not obviously redesign Wilk's method as the Examiner has alleged.

CONCLUSION

For all the reasons advanced above, reversal of the Examiner's Rejection and allowance of all pending claims is solicited.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: 

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(VIII) CLAIMS APPENDIX

1. (Previously presented) A method for accessing an interior of a cavity of a mammal, said method comprising:

positioning an elongated flexible conduit to extend from an exterior of the mammal through a natural orifice into and along at least a portion of the digestive tract to a target wall segment in the digestive tract;

forming an incision in said target wall segment;

advancing a distal end of said flexible conduit so that the distal end of said conduit extends through said wall;

after forming said incision and advancing the distal end of said flexible conduit through said wall, anchoring said distal end with respect to said wall;

advancing an endoscope through said conduit so that a distal end of said endoscope is disposed adjacent or distal to said distal end of said conduit;

viewing at least one of a tissue and an organ within said cavity;

releasing said anchor;

withdrawing said conduit and said endoscope through said wall; and

closing said incision,

further comprising, after said forming an incision and before said advancing said conduit, dilating said incision to facilitate passage of said conduit therethrough, wherein said dilating comprises dilating with an inflatable balloon.

2. (Original) A method as in claim 1, wherein an endoscope is disposed within said conduit during said positioning step and wherein said endoscope is manipulated to guide and direct said flexible conduit to said target wall segment.

Claim 3. (Canceled)

4. (Original) A method as in claim 1, wherein said cavity is the peritoneal cavity.

5. (Previously presented) A method as in claim 4, wherein a proximal end of said flexible conduit comprises a valve housing including a valve structure for defining a substantially air tight seal about said endoscope disposed therethrough and having a gas injection port, and wherein said method further comprises injecting a gas through said gas injection port so as to insufflate the peritoneal cavity after said anchoring step.

6. (Previously presented) A method as in claim 1, wherein said flexible conduit has a pair of anchoring balloons defined adjacent a distal end thereof, and wherein said anchoring comprises inflating said anchoring balloons so that a proximal said balloon is disposed within said digestive tract and a distal said balloon is disposed in the cavity, thereby to capture said wall therebetween.

7. (Previously presented) A method as in claim 1, further comprising, after said viewing, performing at least one endoscopic surgical procedure in said cavity.

8. (Original) A method as in claim 7, wherein said at least one surgical procedure comprises organ removal.

9. (Previously presented) A method as in claim 1, wherein said closing comprises applying a mechanical fastener to at least partly close said incision.

10. (Previously presented) A method as in claim 9, wherein said applying comprises applying a ligating clip to close at least a portion of said incision.

11. (Previously presented) A method as in claim 10, wherein said applying comprises disposing a clip applicator through an accessory channel of said endoscope, engaging a clip disposed at a distal end of said clip applicator with tissue on each lateral side of said incision and actuating said clip so as to clamp said tissue and close said incision.

12. (Previously presented) A method as in claim 1, wherein said forming comprises forming an incision with an endoscopic knife device.

13. (Previously presented) A method as in claim 12, wherein said endoscopic knife device comprises a needle-knife, and wherein said forming comprises cutting said target wall segment with said needle-knife.

14. (Previously presented) A method as in claim 13, wherein said endoscopic knife device is operatively coupled to an electrical source for heating said needle-knife and further comprising actuating said electrical source to heat said needle-knife.

15. (Previously presented) A method as in claim 13, wherein said endoscopic knife device further comprises a conduit within which said needle-knife is disposed, and wherein said needle-knife can be selectively extended to project from a distal end of said conduit and selectively retracted so as to be disposed within said conduit and wherein said needle knife is mounted so as to be selectively removable through a proximal end of said needle-knife conduit and wherein said method further comprises, before said forming, extending said needle-knife to project from said distal end of said conduit, and after said forming step retracting said needle-knife.

16. (Previously presented) A method as in claim 12, further comprising, after said forming, advancing a distal end of said endoscopic knife device through said incision.

17. (Previously presented) A method as in claim 15, further comprising, after said forming, advancing the distal end of said endoscopic knife device through said incision.

18. (Original) A method as in claim 17, further comprising removing said needle-knife from said needle-knife conduit and feeding a guide wire through said needle-knife conduit.

19. (Previously presented) A method as in claim 18, wherein said endoscopic knife device further comprises an inflatable balloon provided adjacent said distal end of said needle-knife conduit, and further comprising, after said advancing of said endoscopic knife device through said incision, inflating said inflatable balloon to dilate said incision.

Claim 20. (Canceled)

21. (Original) A method as in claim 1, wherein said target wall segment is a portion of the stomach wall.

22. (Previously presented) A method as in claim 1, wherein said positioning said flexible conduit comprises positioning said flexible conduit through the patient's oral cavity and esophagus.

Claims 23-35. (Canceled)

36. (Previously presented) A method as in claim 1, wherein said method is performed in the absence of an incision in the abdominal wall.

(IX) EVIDENCE APPENDIX

(NONE)

(X) RELATED PROCEEDINGS APPENDIX

(NONE)